IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
Plaintiffs,	)	Case No.: 08-cv-7231 (consolidated with no. 09-cv-6053)
v.	)	Judge Robert M. Dow, Jr.
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company LLC (collectively "Pfizer") filed this patent infringement action against Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") for infringement of United States Patent No. 5,273,995 ("the '995 patent"). The suit was prompted by Apotex's filing of an Abbreviated New Drug Application ("ANDA"), in which it seeks permission from the Food and Drug Administration ("FDA") to market a generic version of Pfizer's pharmaceutical product, Lipitor®. Currently before the Court is Apotex's motion to dismiss [34, docket no. 09-6053] Pfizer's claim for infringement of the '995 patent for lack of subject matter jurisdiction and for failure to state a claim pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). For the reasons stated below Apotex's motion is denied.[1]

[1] The denial of Apotex's motion is subject to the condition that, within 30 days of the entry of this order, Pfizer agree to issue a terminal disclaimer stating that the '667 reissue patent and the '995 patent shall remain commonly owned. The terminal disclaimer is necessary to obviate any obviousness-type double patenting problems that currently exist between the '667 reissue patent and the '995 patent, and, in

I. Background

A. Procedure Background

On November 4, 2008, Apotex notified Pfizer that it had filed an Abbreviated New Drug Application ("ANDA") with the FDA to market a generic version of Pfizer's cholesterol-lowering drug Lipitor®. Under the Hatch-Waxman Act of 1984, Pfizer was required to file suit against Apotex within 45 days of receiving that notice in order to obtain a statutorily mandated 30-month stay of FDA approval of Apotex's ANDA. See 21 U.S.C. § 355(j)(5)(B)(iii). On December 17, 2008, Pfizer filed suit against Apotex in Delaware District Court alleging that Apotex's ANDA infringed the '995 patent. Because Pfizer anticipated (correctly) that Apotex would challenge personal jurisdiction in Delaware, Pfizer also filed an identical patent infringement suit in this Court just hours after filing the Delaware action. Pfizer's action against Apotex in this Court was assigned case number 08-cv-7231.

On March 16, 2009, Pfizer moved to stay the proceedings in this case pending the outcome of the jurisdictional dispute in Delaware [43]. This Court granted Pfizer's motion to stay in an order dated June 12, 2009. See [92]. On August 13, 2009, the Delaware court granted Apotex's § 1404(a) transfer motion and ordered the Delaware action transferred to this Court. In light of the Delaware court's transfer order, this Court vacated the stay of case number 08-cv-7231 on August 18, 2009. See [98]. The Delaware action was transferred to this Court on September 28, 2009, was assigned case number 09-cv-6053, and was consolidated with case number 08-cv-7231. See [108].

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particular, to avoid any risk of multiple infringement suits. See 3A CHISUM ON PATENTS § 9.04[2][b][ii] (2010) ("The possibility of multiple suits against an infringer by assignees of related patents has long been recognized as one of the concerns behind the doctrine of double patenting."); 37 C.F.R. § 1.321(c)(3) (providing that obviousness-type double patenting can be obviated by a terminal disclaimer stating that the patent "shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting").

On March 17, 2009 – after the filing of both the Delaware and Illinois actions – the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. RE40,667 ("the '667 patent"). The '667 patent is a reissue patent, which the PTO issued on the basis of the first of two reissue applications filed by Pfizer based on the '995 patent. Following the issuance of the '667 patent, Pfizer filed a first amended complaint [25, docket no. 09-cv-6053] in the Delaware action asserting both the '995 and '667 patents. Pfizer filed a motion for leave to file a first amended complaint in this Court. See [59]. However, this Court did not rule on that motion prior to staying the case. Following the consolidation of the two actions, this Court deemed the amended complaint that was filed in Delaware to be the operative complaint in the consolidated action. See [109].

Prior to the Delaware court's transfer of the action, Apotex had filed a motion to dismiss the first amended complaint. See [34, 35, 40, 47 docket no. 09-6053]. In the interest of efficiency and economy, this Court decided to consider the previously filed Delaware briefs on the motion to dismiss the amended complaint. See [109]. The Court allowed the parties to raise any relevant factual and/or legal developments that had arisen since the prior briefs were filed in a series of short supplemental briefs. See [115, 124, 125, 126]. All of the briefs on this pending motion are oversized, which is appropriate in view of the complexity of the issue raised.

B. Factual Background[2]

On December 28, 1993, the PTO issued the '995 patent, which is identified pursuant to 21 U.S.C. §355 (b)(1) by the United States Food and Drug Administration ("FDA") as covering Pfizer's Lipitor® product. FAC ¶¶ 2, 13. Lipitor® is the brand name for Pfizer's atorvastatin

[2] For purposes of Apotex's motion to dismiss, the Court assumes as true all well-pleaded allegations set forth in the first amended complaint. See, *e.g.*, *Killingsworth v. HSBC Bank Nevada, N.A.*, 507 F.3d 614, 618 (7th Cir. 2007).

calcium medication, which is presently indicated for the prevention of cardiovascular disease and high cholesterol levels in the bloodstream.

In 2006, the United States Court of Appeals for the Federal Circuit held that claim 6 of the '995 patent is invalid as a result of a technical problem in the drafting of the claim, which resulted in a violation of 35 U.S.C. § 112, ¶ 4. See *id.* ¶ 44; *Pfizer, Inc. v. Ranbaxy Laboratories Ltd.*, 457 F.3d 1284, 1291 (Fed. Cir. 2006). Specifically, the court found that claim 6 was an improper dependent claim under § 112, ¶ 4 because it recited subject matter outside the scope of the claim on which it depended. *Pfizer*, 457 F.3d at 1291. Pfizer concedes that the technical defect in claim 6 of the '995 patent also is contained in other claims in the '995 patent.

In an effort to correct the invalidating drafting errors, Pfizer filed two reissue applications based on the '995 patent. Pfizer filed the first reissue application on January 16, 2007 as U.S. Pat. App. No. 11/653,830 ("the '830 reissue application"); it included a corrected claim 6 of the '995 patent and two new claims (claims 13 and 14). Pfizer filed the second reissue application – U.S. Pat. App. No. 11/973,897 ("the '897 continuation reissue application") – on October 10, 2007, while the '830 reissue application was still pending. The second reissue application is a continuation reissue application of the '830 reissue application; it includes all of the claims of the '995 patent except for claim 6, as well as one new claim. According to Pfizer, the '830 reissue application was limited to corrected claim 6 (and the two new claims) in order to expedite its reissue.

On March 17, 2009, the PTO issued the '830 reissue application as the '667 reissue patent. FAC ¶¶ 3-4. Like the '995 patent, the '667 patent covers Pfizer's Lipitor® product. Claim 6 of the '667 patent is identical in scope to claim 6 of the '995 patent, but is an

independent claim. *Id.* ¶ 45. As far as the Court is aware, the '897 continuation reissue application remains pending before the PTO; no party has advised the Court to the contrary.

By letter dated November 4, 2008, Apotex notified Pfizer that it had filed an ANDA seeking approval from the FDA to engage in the commercial manufacture, use, and sale of a generic version of atorvastatin (the drug Pfizer markets as Lipitor®) prior to the expiration of the '995 patent. *Id.* ¶¶ 18, 47. The letter asserted that the '995 patent was invalid, unenforceable and/or not infringed by Apotex's proposed ANDA product. *Id.* ¶ 21. In the claim for infringement of the '995 patent, of which Apotex seeks dismissal, Pfizer alleges that Apotex infringed the '995 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium prior to the expiration of the '995 patent. *Id.* ¶ 50.

II. Legal Standards

Apotex has moved to dismiss Pfizer's claim for infringement of the '995 patent for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), and for failure to state a claim under Rule 12(b)(6). The purpose of a motion to dismiss is not to decide the merits of the case. A Rule 12(b)(6) motion tests the sufficiency of the complaint, *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990), while a Rule 12(b)(1) motion tests whether the Court has subject matter jurisdiction. *Long v. Shorebank Development Corp.*, 182 F.3d 548, 554 (7th Cir.1999). In reviewing a motion to dismiss under either rule, the Court takes as true all factual allegations in Pfizer's complaint and draws all reasonable inferences in its favor. *Killingsworth*, 507 F.3d at 618; *Long*, 182 F.3d at 554.

To survive a Rule 12(b)(6) motion to dismiss, the complaint first must comply with Rule 8(a) by providing "a short and plain statement of the claim showing that the pleader is entitled to

relief" (Fed. R. Civ. P. 8(a)(2)), such that the defendant is given "fair notice of what the * * * claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Second, the factual allegations in the complaint must be sufficient to raise the possibility of relief above the "speculative level," assuming that all of the allegations in the complaint are true. *E.E.O.C. v. Concentra Health Servs., Inc.*, 496 F.3d 773, 776 (7th Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). "Detailed factual allegations" are not required, but the plaintiff must allege facts that, when "accepted as true, * * * 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, --- U.S. ----, 129 S.Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 555). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S.Ct. at 1949. "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Twombly*, 550 U.S. at 563. Surviving a Rule 12(b)(1) motion to dismiss is more difficult, as Plaintiff bears the burden of proving that the jurisdictional requirements have been met. *United Phosphorus, Ltd. v. Angus Chem. Co.*, 322 F.3d 942, 946 (7th Cir. 2003).

III. Analysis

Apotex seeks dismissal of Pfizer's claim for infringement of the '995 patent on the ground that Pfizer surrendered the '995 patent as a matter of law when the '667 reissue patent was issued. According to Apotex, the partial reissue of the '995 patent as the '667 patent resulted in the surrender of the '995 patent, such that the '995 patent is entirely unenforceable by Pfizer. Apotex argues that, in view of the surrender of the '995 patent, no Article III case or controversy exists between the parties with respect to the '995 patent. Accordingly, Apotex

contends, this Court lacks subject matter jurisdiction over the '995 infringement claim and dismissal pursuant to Rule 12(b)(1) is appropriate. Alternatively, Apotex submits that Pfizer's claim based on the '995 patent should be dismissed for failure to state a claim under Rule 12(b)(6) because Pfizer cannot assert a claim to enforce an unenforceable patent.

Pfizer responds that the issuance of the '667 reissue patent did not result in the surrender of the '995 patent because a second reissue application (the '897 reissue application) based on the '995 patent remains pending before the PTO. According to Pfizer, the surrender of an original patent occurs when the last reissue patent is granted, not the first as Apotex contends. Pfizer maintains that the '995 patent will not be surrendered until the pending '897 continuation reissue application is granted, and thus the '995 patent remains enforceable. In short, the dispute between the parties concerns the timing of the surrender of an original patent where an applicant has filed multiple reissue applications based on that original patent.

A. Reissue Provisions of The Patent Act

Before addressing the parties' dispute, a brief discussion of the relevant portions of the Patent Act is in order. The reissue provisions of the Patent Act permit the correction of certain defects in previously issued patents. Section 251 sets forth the requirements for the reissuance of a defective patent. In paragraph 1 it states:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partially inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, *the Director shall, on the surrender of such patent* and the payment of the fee required by law, *reissue the patent* for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

35 U.S.C. § 251 ¶ 1 (emphasis added). Section 252, which addresses the effects of reissue, contains the Patent Act's only other reference to the surrender of an original patent through

reissue. It provides, in part, that "[t]he surrender of the original patent shall take effect upon the issue of the reissued patent." 35 U.S.C. § 252 ¶ 1. See also 37 C.F.R. § 1.178(a) ("the surrender shall take effect upon reissue of the patent"); *National Business Systems, Inc. v. AM Intern., Inc*., 546 F. Supp. 340 (N.D. Ill. 1982), *affirmed and remanded*, 743 F.2d 1227 (7th Cir. 1984), *on remand*, 607 F. Supp. 1251 (N.D. Ill. 1985) ("the time for surrendering an original patent in reissue proceedings occurs when the reissue patent is granted"). Consequently, while a reissue application is pending, the original patent remains in effect. 37 C.F.R. § 1.178(a). And if a reissue application is refused, "the surrender never takes effect, and the patent stands as if no application had ever been made for a reissue." *Allen v. Culp*, 166 U.S. 501, 505 (1897).

Once the original patent is surrendered, it "cannot be infringed" because "[t]he original claims are dead." *Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 827 (Fed. Cir. 1984). Therefore, where a patentee seeks to surrender an original patent in favor of a single reissue patent, the matter is very straightforward: the surrender of the original patent takes effect when the reissue patent is granted, and after reissue, the original patent is no longer enforceable. In other words, in the case of a single reissue patent, surrender and reissuance go hand-in hand, and the original patent is invalid after the date of reissue. The parties do not dispute that characterization of the law.

The dispute arises in the context of multiple reissue applications based on a single original patent. The reissue provisions expressly allow for the issuance of "several reissued patents for distinct and separate parts of the thing patented, upon demand of the applicant, and upon payment of the required fee for a reissue for each of such reissued patents." 35 U.S.C. § 251 ¶ 2. See also 37 C.F.R. § 1.177(a) ("The Office may reissue a patent as multiple reissue patents."); *In re Graff*, 111 F.3d 874, 876 (Fed. Cir. 1997) ("§ 251 does not bar multiple reissue

patents in appropriate circumstances"). And the Federal Circuit has held that multiple reissue patents based on a single original patent may issue consecutively, as opposed to simultaneously. *Graff*, 111 F.3d at 876-77 (rejecting Board of Patent Appeals and Interferences's conclusion that where a reissue patent has issued, 35 U.S.C. § 251 does not authorize the grant of a second, later reissue patent stemming from the same original patent).

The question before the Court is when the surrender of the original patent takes effect (thereby rendering the original patent unenforceable) where an applicant seeks multiple reissue patents which do not issue at the same time. That question requires the Court to engage in statutory construction. In construing the Patent Act, as in all statutory construction cases, the Court must discern Congress's intent by looking first to the language it used in the statute. *U.S. v. Rosenbohm*, 564 F.3d 820, 823 (7th Cir. 2009). If "the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case," and the statutory scheme is consistent, then the Court's inquiry is complete. *Robinson v. Shell Oil Co*., 519 U.S. 337, 340 (1997). "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Id.* at 341 (citation omitted). Put differently, simply because the text of a statute is susceptible to two meanings does not render it ambiguous, *Valero Energy Corp. v. U.S.*, 569 F.3d 626, 632 (7th Cir. 2009), because, often, the structure of the statute as a whole provides significant guidance as to Congress's intent, *Ortega v. Holder*, 592 F.3d 738, 743 (7th Cir. 2010). If the statutory language remains ambiguous, the Court may turn to the legislative history to further elucidate Congress's intent. *In re Swanson*, 540 F.3d 1368, 1376 (Fed. Cir. 2008).

B. Statutory Language

Apotex argues that the plain language regarding surrender in § 251 ¶ 1 and § 252 ¶ 1 ("the surrender clauses") requires that surrender occur when the first reissue patent issues. See 35 U.S.C. § 251 ¶ 1 ("the Director *shall*, on the surrender of such patent * * *, reissue the patent for the invention disclosed in the original patent") (emphasis added); 35 U.S.C. § 252 ¶ 1 ("[t]he surrender of the original patent *shall* take effect upon the issue of the reissued patent") (emphasis added). According to Apotex, the use of the word "shall" in each provision demonstrates that surrender at the time of reissue is mandatory, such that surrender of the original patent is a prerequisite to the issuance of a reissue patent. Apotex concludes that, because surrender is a prerequisite to any reissue, in the context of multiple reissue patents, surrender must take effect upon the issuance of the first reissue patent.

The Court agrees that the statutory language does not appear to allow for a patent to reissue prior to an effective surrender, as Pfizer would have this Court conclude. But it is equally true that the statutory language does not, on its face, require the surrender of an original patent before it is reissued. And yet, under the Apotex's construction, Pfizer would be deemed to have surrendered its original patent before some of the claims in that patent are reissued. Thus, the plain language of the surrender clauses – at least when viewed in isolation – does not clearly support either party's interpretation. Rather, the surrender clauses appear to contemplate surrender and reissuance occurring simultaneously. Of course, in the context of multiple reissues, that simply is not possible (at least if Apotex's assertion that there can be only one surrender is correct, an issue addressed more thoroughly below). The Court sees nothing in the plain language of the surrender clauses in §§ 251 and 252 that clearly establishes whether Congress intended for surrender to accompany the first reissue patent or the final one. Under

these circumstances, the statutory language is ambiguous. Accordingly, the Court must look beyond the particular language being construed for guidance as to Congress's intent.

C. The Statutory Scheme

The Court begins by considering the context provided by related provisions of the Patent Act. See *Bayer AG v. Housey Pharmaceuticals, Inc*., 340 F.3d 1367, 1372 (Fed. Cir. 2003) ("In order to resolve the ambiguity in the statutory language, we look first to other provisions of the statute."); *Pollard v. E.I. du Pont de Nemours & Co.*, 532 U.S. 843, 852 (2001) (courts must look to the provisions of the whole law to determine a term's meaning, rather than analyzing the term in isolation). Pfizer contends that two other clauses in § 252 ¶ 1 – the so-called abatement and continuation clauses – provide the relevant context here, and demonstrate that surrender does not occur until all of the reissue applications are issued.

The abatement clause provides that "in so far as the claims of the original and reissued patents are substantially identical, such surrender shall not affect any action then pending nor abate any cause of action then existing." 35 U.S.C. § 252 ¶ 1. The continuation clause states that "the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent." *Id.* Pursuant to these clauses, the "patentee's rights under the original patent continue after reissue insofar as the claims of the original and reissue patents are identical." 4A Donald S. Chisum, CHISUM ON PATENTS § 15.01 (2010). See also *Seattle Box*, 731 F.2d at 826 ("35 U.S.C. § 252 * * * allows claims in a reissue patent to reach back under certain circumstances to the date the original patent issued"); *Kaufman Co., Inc. v. Lantech, Inc.*, 807 F.2d 970, 976 (Fed. Cir. 1986) ("if the claims in the original and reissued patents are 'identical,' the reissued patent is deemed to have effect from the date of the original patent"). The purpose

of these clauses is relatively clear – namely, to preserve an inventor's property right (with respect to identical claims) where a mere error in drafting requires reissuance of the patent.

Here, Apotex asks this Court to dismiss a pending action – Pfizer's '995 infringement claim – on the ground that the '995 patent was surrendered when the '667 reissue patent issued. Pfizer contends that, because there are claims in the pending '897 reissue application that are identical to original claims in the '995 patent, dismissal is inconsistent with the purpose of the abatement and continuation clauses.[3] The Court agrees. Granting Apotex's motion to dismiss would cut off Pfizer's rights under all claims in the '995 patent – save for claim 6 – thereby allowing the reissue procedure to destroy a portion of Pfizer's property rights. Such a result is plainly contrary to the purpose of the abatement and continuation clauses.

Like the abatement and continuation clauses, the surrender clauses can be read as seeking to preserve an inventor's rights by requiring surrender only upon reissuance. Indeed, the Federal Circuit has held that "the purpose of the reissue statute is to avoid forfeiture of substantive rights." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1575 (Fed. Cir. 1991), *overruled on other grounds by Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (*en banc*); see also *In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986) ("The [reissue] statute is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally"). Pfizer's reading of the reissue provisions, which avoids forfeiture by

[3] Pfizer also argues that Apotex's interpretation violates the abatement clause. It is not clear that dismissal of the '995 infringement claim would violate the letter of the abatement clause, which applies "in so far as the claims of the original and reissued patents are substantially identical." 35 U.S.C. § 252 ¶ 1. Here, the only reissued patent in existence is the '667 patent, as the '897 reissue application remains pending. And dismissal would not affect any causes of action based on identical claims in the '995 patent and the '667 reissue patent. Rather, it is causes of action based on claims in the pending application that would be affected. But the abatement clause does not address identical claims in the original patent and a reissue application. In any event, the Court need not decide whether Apotex's reading of the statute would result in a violation of the abatement clause.

postponing surrender of the original patent until all reissue applications have been granted, better accords with the statutory purpose than Apotex's proposed construction.

D. Legislative History

The legislative history of the reissue provisions confirms the conclusion that Congress intended to preserve inventors' property rights where reissuance is required because of a technical defect in drafting.[4] The history of the reissue provisions dates back to 1832 when, in response to the Supreme Court's decision in *Grant v. Raymond*, 31 U.S. 218 (1832), in which the Court recognized the authority of patent officials to reissue a defective original patent, Congress first codified the power to grant reissues. 4A CHISUM ON PATENTS § 15.02 (2010). Until 1870, courts interpreted the reissue provision as requiring an original patent to be deemed surrendered upon the filing of an application for reissue. *Id.*; see also *Allen v. Culp*, 166 U.S. 501, 504 (1897) ("it was uniformly held by this court that the surrender of the patent for reissue was a legal cancellation and extinguishment of it, that no rights could afterwards be asserted upon it, and that suits pending for an infringement of such patent fell with its surrender, because the foundation upon which they were begun no longer existed"). In 1870, Congress amended the Patent Act to specify that "the surrender [of the original patent] shall take effect upon the issue of the amended patent." *Allen*, 166 U.S. at 505. According to the Supreme Court, Congress clarified the timing of surrender "[t]o obviate the injustice to inventors occasioned by the peremptory requirement that the patent should be treated as extinguished from the moment it was surrendered for a reissue." *Id.* Thus, the legislative history makes clear that, in enacting the language that now appears in § 252 ¶ 1 ("[t]he surrender of the original patent shall take effect upon the issue of the

[4] See *Barber By and Through Barber v. U.S.*, 676 F.2d 651, 655-56 (Ct. Cl. 1982) ("In seeking to ascertain the legislative purpose, it is proper to look at the circumstances existing at the time of the enactment of the statute, to the necessity for the law, the evils intended to be cured by it, to the intended remedy, and to the law as it existed prior to such enactment.").

reissued patent"), Congress intended to safeguard patentees' rights while reissue applications are pending.

The abatement and continuation clauses discussed above first were codified in the Patent Act of 1928. 4A CHISUM ON PATENTS § 15.02 (2010). According to the Senate report from the Committee on Patents, Congress intended those clauses "to correct an almost unbelievable and inequitable situation" – namely, that "[u]nder the present law if a patentee applies for a reissue, no matter for what purpose, all rights he had in and under the original patent are forfeited *ab initio* upon the grant of the reissue." S. Rep. No. 567, at 1, 70th Cong., 1st Sess. (1928) (Conf. Report). See also *Howes v. Medical Components, Inc.*, 814 F.2d 638, 645 (Fed. Cir. 1987) ("Congress intended * * * to ameliorate the harsh effect of a patent's surrender, which, prior to the adoption of the rule now incorporated in § 252, required dismissal, for failure to state a cause of action, of any action filed before the patent was surrendered.").

Again, the legislative history supports the Court's conclusion that, in enacting the reissue provisions, Congress intended to avoid the inequity associated with cutting off an inventor's property right in a patent as a result of a drafting defect requiring reissue. As noted above, Apotex's interpretation of the reissue provisions, under which Pfizer loses its rights under portions of the '995 patent, undermines Congress's intent. By contrast, Pfizer's construction is consistent with Congress's goal of preserving patentees' rights.

E. The Board of Patent Appeals and Interferences's *Okamoto* Decision

In further support of its position, Pfizer directs the Court to *Ex Parte Okamoto*, 2006 WL 2523548 (B.P.A.I. Oct. 21, 2002), a decision issued by the Board of Patent Appeals and Interferences ("BPAI" or "Board") addressing the very issue before the Court – the timing of surrender in the case of multiple, non-simultaneous reissues. In *Okamoto*, the BPAI adopted the

statutory construction advanced by Pfizer, concluding that "the surrender of a defective patent does not occur until all of the continuation or divisional reissue applications are issued." 2006 WL 2523548, at *4. The parties spill considerable ink – including numerous supplemental briefs – debating the level of deference to which the Board's decision is entitled. Therefore, before discussing the Board's reasoning, the Court will address the appropriate weight to be accorded to BPAI decisions.

The parties agree that Congress has authorized the PTO to promulgate regulations directed to the conduct of proceedings before it, but has not authorized the PTO to issue substantive rules. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) ("the broadest of the PTO's rulemaking powers – 35 U.S.C. § 6(a) – authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the [PTO]'; it does NOT grant the Commissioner the authority to issue substantive rules"); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1335-36 (Fed. Cir. 2008) (PTO has authority to issue procedural rules, but not substantive ones). Therefore, PTO regulations are entitled to deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) only to the extent that they are procedural. See *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 649 (1990) ("A precondition to deference under *Chevron* is a congressional delegation of administrative authority."). Pfizer contends that the timing of the surrender of an original patent in the context of multiple reissue patents is procedural, such that the Board's decision in *Okamoto* is entitled to *Chevron* deference. Apotex takes the position that when an original patent is surrendered is substantive in nature, and therefore the *Okamoto* decision should not be accorded deference.

The parties fail to appreciate the distinction between Board decisions and PTO rules and regulations for purposes of the deference analysis. Pfizer argues that administrative deference is

not limited to notice-and-comment rulemaking procedures, and must be extended to Board decisions. While Pfizer is correct that judicial review of the Board's decisions is governed by the Administrative Procedure Act ("APA"), see *In re Sang-Su Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002) ("Tribunals of the PTO are governed by the Administrative Procedure Act, and their rulings receive the same judicial deference as do tribunals of other administrative agencies"), that standard of review simply is not relevant here. First, because this Court is not reviewing the Board's *Okamoto* decision, the proper standard of review is not germane. Second, even under the APA standard, the Board's legal conclusions are not entitled to deference. *In re Chapman*, 595 F.3d 1330, 1337 (Fed. Cir. 2010) (in reviewing PTO decisions under the APA standard, "we review Board's legal conclusions without deference, and review its findings of fact to determine if they are supported by substantial evidence."). Moreover, the Court notes that, contrary to Pfizer's apparent contention, the standard of review applied to agency decisions under the APA is not equivalent to the deference accorded to agency positions under *Chevron*.

Notwithstanding the parties' claims to the contrary, Board decisions are not entitled to *Chevron* deference, regardless of whether they concern procedural or substantive issues. Rather, federal courts treat BPAI decisions as persuasive, non-binding authority. See *Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004) ("decision[s] from the Board of Patent Appeals and Interferences * * * may be persuasive but [are] not binding precedent on this court"); *In re Swanson*, 540 F.3d 1368, 1375 n.3 (Fed. Cir. 2008) ("While the Board's statutory interpretation in a particular case is given no deference, deference may be owed to the PTO's interpretation of statutory provisions concerning 'the conduct of proceedings in the Office,' 35 U.S.C. § 2(b)(2)(A), made pursuant to its rulemaking authority under 35 U.S.C. § 2(b)(2)(A)."); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1163 (Fed. Cir. 2006) (while not binding, "Board

decisions nevertheless represent the views of a panel of specialists in the area of patent law"). Accordingly, consistent with the apparent weight of authority, the Court will consider the decision as persuasive authority.

In the *Okamoto* decision, the Board concluded that "the surrender of a defective patent does not occur until all of the continuation or divisional reissue applications are issued consistent with Section 251, paragraphs 2 and 3." 2006 WL 2523548 at *4. According to the Board, its conclusion was "[i]mplicit" in the Federal Circuit's *In re Graff* opinion, which also involved multiple reissue patents. In *Graff*, the patentee originally filed a single reissue application. 111 F.3d at 875. The examiner allowed some claims in the reissue application and rejected others. *Id.* In order to expedite the reissue of the allowed claims, the patentee cancelled the rejected claims and re-presented them in a continuation reissue application; the allowed claims issued in a first reissue patent. *Id.* at 876. The examiner rejected the continuation reissue application. *Id.* The Board affirmed on multiple grounds, including that "35 U.S.C. § 251 does not authorize reissuance of the surrendered [original] patent through the present second reissue application." *Id.*

On appeal, the Federal Circuit rejected that BPAI's conclusion that a second reissue application could not issue, reasoning that "§ 251 does not bar multiple reissue patents in appropriate circumstances" and that the "statute does not prohibit divisional or continuation reissue applications, and does not place stricter limitations on such applications when they are presented by reissue, provided of course that the statutory requirements specific to reissue applications are met." 111 F.3d at 876-77. The *Graff* court did not explicitly address *when* the

surrender of the original patent took effect.[5] According to the BPAI in *Okamoto*, that surrender must not take effect until the final reissue is "implicit" in the *Graff* holding.

In sum, the reissue provisions read as a whole, the purpose underlying those provisions, the legislative history, and the BPAI's reading of the statute support Pfizer's contention that full surrender of an original patent is not required upon the issuance of the first of multiple reissue patents. However, Apotex argues that Pfizer's interpretation nevertheless must be rejected because it cannot be squared with the long-standing ban on double patenting. The Court addresses this objection below.

F. Ban on Double Patenting

Courts have interpreted the Patent Act to forbid a second patent from covering the same invention or an obvious variation of it, in order to prevent patentees from extending the duration of their patents by patenting the same subject matter more than once. The proscription against double patenting "takes two forms: statutory and non-statutory." *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005). Statutory double patenting is based on § 101 of the Patent Act, under which an inventor is entitled to a single patent for an invention. *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993). Non-statutory double patenting, which is also referred to as "obviousness-type" double patenting, "is a judicially created doctrine adopted to prevent claims in separate applications or patents that do not recite

[5] Apotex seizes on the *Graff* court's reference to the original patent as "the *surrendered* '928 patent" to argue that the *Graff* decision supports its position that surrender occurs upon the issuance of the first reissue patent. But courts regularly refer to original patents for which a reissue application is pending as "surrendered." See *Allen*, 166 U.S. at 505 ("When a patent is thus surrendered, there can be no doubt that is continues to be a valid patent until it is reissued, when it becomes inoperative"); *American Telephone & Telegraph Co. v. Milgo Electronic Corp.*, 416 F.Supp. 951, 953 (D.C.N.Y. 1976) ("the surrender of a patent and the filing of a reissue application has no impact on the existence of that patent * * * The reissue statute as well as the Patent Office Rules require surrender of the original patent before a reissue patent may be granted[,] * * * [but] the surrender of the original patent does not take effect until the issuance of the reissue patent"). Therefore, the court's reference to the original patent as "surrendered" does not imply that a full surrender had taken effect, as Apotex argues.

the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *Perricone*, 432 F.3d at 1373.

Apotex contends that, in this case, any holding that the '995 patent was not surrendered when the '667 reissue patent issued would run afoul of the ban on double patenting. In particular, Apotex argues that because claim 6 of the '667 patent covers exactly the same subject matter that claim 6 of the '995 patent, the two patents cannot both be valid without violating the ban on statutory double patenting. Apotex further contends that claims 13 and 14 of the '667 patent are obvious modifications of claims 11 and 12 of the '995 patent, and thus present an "obviousness-type" double patenting problem.

Pfizer responds that the existence of claim 6 in each patent does not violate the ban on double patenting because claim 6 of the '995 patent has been found to be invalid. Therefore, only one claim 6 – the one in the '667 reissue patent – is enforceable. The Court agrees.

Pfizer does not specifically address Apotex's argument regarding claims 13 and 14 of the '667 patent, but argues generally that the purpose of the double patenting ban is not implicated in the context of reissue patents, which have the same the term as the original patent. As Pfizer notes, "[t]he primary purpose of the double patenting doctrine is to prevent the extension of the statutory period of monopoly that would occur if successive patents were allowed on the same basic concept." 3A CHISUM ON PATENTS § 9.01 (2010); see also *Takeda Pharmaceutical Co., Ltd. v. Doll*, 561 F.3d 1372, 1375 (Fed. Cir. 2009) ("the double patenting doctrine is designed to prevent 'unjustified timewise extension of the right to exclude'") (citation omitted). The Court agrees that reissue patents do not implicate that purpose because a reissue patent has the same term as the original patent. However, as Apotex notes, the ban on "obviousness-type" double patenting also serves another purpose – preventing multiple infringement suits by assignees of

related patents. See *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009) (noting that "harassment by multiple assignees" provides "a second justification for obviousness-type double patenting"); 3A CHISUM ON PATENTS § 9.04[2][b][ii] (2010) ("The possibility of multiple suits against an infringer by assignees of related patents has long been recognized as one of the concerns behind the doctrine of double patenting."). The concern that related patents might be enforced by different owners is reflected in the PTO regulations, which provide that obviousness-type double patenting can be obviated by a terminal disclaimer stating that the patent "shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting." 37 C.F.R. § 1.321(c)(3); see also *In re Van Ornum*, 686 F.2d 937, 944-48 (CCPA 1982) (finding common ownership requirement set forth in 37 § C.F.R. 1.321 to be valid, reasoning that it is "desirable to tie both the termination and the ownership of the two patents together").

The Manual of Patent Examining Procedures ("MPEP") addresses the possibility of double patenting in the context of multiple reissue applications, and continuation reissue patents in particular. The MPEP states that "[w]here the parent reissue application issues before the examination of the continuation reissue application, the claims of the continuation reissue application should be carefully reviewed for double patenting over the claims of the parent reissue application." MPEP 8th Ed., Rev. 7, § 1451 (2008).[6] Thus, the MPEP speaks to potential double patenting between multiple reissue patents. However, it does not appear to contemplate the issue raised by Apotex – the potential of double patenting between the original patent and one of the reissue patents. The reason that the MPEP fails to address that possibility

[6] While the MPEP is "not binding on this court, [it] may be given judicial notice to the extent [that it] do[es] not conflict with the statute." *Enzo Biochem v. Gen-Probe*, 323 F.3d 956, 964 (Fed. Cir. 2002) (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995)).

may be that such double patenting is unlikely in light of the MPEP's apparent endorsement of partial surrender. See *id.* ("[o]nce a claim in the patent has been reissued, it does not exist in the original patent; thus, it cannot be reissued from the original patent in another reissue application"). The MPEP appears to take the position that, in the case of multiple reissue patents, individual claims of the original patent are surrendered whenever they are reissued.[7] A policy of partial surrender would obviate the risk of statutory double patenting between an original patent and a reissue patent. However, partial surrender (which Pfizer advocates as an alternative interpretation) does not solve the problem of obviousness-type double patenting raised by Apotex.

Thus, Apotex's arguments regarding obviousness-type double patenting involving claims 13 and 14 of the '667 patent and claims 11 and 12 of the '995 patent appear to be valid to the extent that Apotex could face multiple infringement suits by different parties if Pfizer were to assign the '667 reissue patent or the '995 patent to another party. Pfizer, somewhat tellingly, does not address the obviousness-type double patenting issue, and therefore gives the Court no reason to doubt Apotex's concerns. However, the risk of multiple infringement suits can be addressed by a terminal disclaimer stating that the '667 reissue patent and the '995 patent shall remain commonly owned.[8] To the extent that Pfizer is willing to issue such a terminal

[7] As noted, the MPEP can be interpreted as approving a policy of partial surrender, whereby individual claims are deemed to have been surrendered (and thus to be unenforceable) once they are reissued. Alternatively, the MPEP may simply be read as recognizing the long-held understanding that once a claim has been reissued, the original claim is dead. See *Seattle Box Co.*, 731 F.2d at 827. To the extent that the claims in a reissued patent are identical to the claims in the original patent, the difference between partial surrender and full surrender upon the issuance of the final reissue patent is really a question of semantics. As a practical matter, once a claim is reissued, the identical original claim no longer can be enforced; it has been replaced by the identical reissued claim.

[8] The Federal Circuit has recognized that a terminal disclaimer can overcome obviousness-type double patenting so long as the patents are commonly owned. See *In re Fallaux*, 564 F.3d at 1319 (Fed. Cir. 2009) ("If the Fallaux application and the Vogels patents were commonly owned, the terminal disclaimer filed in this case would have been effective to overcome the double patenting rejection"); *In re Longi*, 759

disclaimer, the Court's conclusion that full surrender of the '995 patent did not occur upon the issuance of the '667 reissue patent is not at odds with the ban on double patenting.

IV. Conclusion

For the foregoing reasons, Apotex's motion to dismiss [34] is denied on the condition that within 30 days of the entry of this order Pfizer issues a terminal disclaimer stating that the '667 reissue patent and the '995 patent shall remain commonly owned.

Dated: June 30, 2010

Robert M. Dow, Jr.
United States District Judge

F.2d 887, 894 (Fed. Cir. 1985) ("It is well-established that a *common assignee* is entitled to proceed with a terminal disclaimer to overcome a rejection based on double patenting of the obviousness type") (emphasis added). That litigation is on-going does not preclude Pfizer from issuing a terminal disclaimer. See *Boehringer Ingelheim Intern. GmbH v. Barr Laboratories, Inc*., 592 F.3d 1340, 1347 (Fed. Cir. 2010) ("a patentee may file a disclaimer after issuance of the challenged patent or during litigation, even after a finding that the challenged patent is invalid for obviousness-type double patenting"); *Perricone v. Medicis Pharm. Corp*., 432 F.3d at 1375 (noting that there is no "prohibition on post-issuance terminal disclaimers" and that "[a] terminal disclaimer can indeed supplant a finding of invalidity for double patenting").